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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,308

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Lars Winther

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DAKO/FINNEGAN, HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

SASAKI, SHOGO

ART UNIT

PAPER NUMBER

1773

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DELIVERY MODE

04/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,308	WINTHER ET AL.	
	Examiner	Art Unit	
	Shogo Sasaki	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 40-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/15/2011 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/15/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendments to the claims; the specification; and the drawings are acknowledged.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/15/2011 has been entered.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

This application claims priority to other applications, thus, for clarification purposes, the examiner will address the effective filing date granted to the presently pending claims. The present claims find the earliest support only in prior PCT application, PCT/US03/40520. That is the first instance in the priority chain in which a processing system including a climate control device; a data processing device for controlling the climate control device; and a sensor device providing feedback signal to

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the climate control device is disclosed. Therefore, the present claims are granted an effective filing date of 12/19/2003.

Claim Interpretations

4. Claims 1 and 40 do not positively set forth "a processing protocol" as part of the claimed subject matter. Any further references (e.g., "according to the protocol" in claims 9 and 48) to said element were not given patentable weight even if those references further limit said unclaimed element. The data processing device as recited is *for storing* a processing protocol. The claims do not recite that the device contains a protocol. For instance, a processor (normally equipped with cache) is capable of storing any information. Said protocol is not limited to any specific instructions.

5. Regarding claims 1 and 40, the term "section" does not inherently impart any specific structural requirement. It is somewhat unclear how such a section can be labeled or referenced a "sample processing" or "staining" portion of the apparatus. The elements of said claims do not structurally limit the section to a particular processing or staining structures. The phrases "sample processing" or "staining" implies the intended use of said sections. The term section was interpreted to mean a portion of the housing that may be used for processing or staining a sample; and is capable of accommodating a slide.

6. Regarding the last 2 wherein clauses in claims 1 and 40, it is noted that the phrase "may be" is not a requirement for the claims, but said phrase makes the recitations optional. Furthermore, said clauses are directed to intended use/function of

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the claimed apparatus. The structure of the device is not defined or structurally limited by the intended use/function. It should be noted that one is not required to use the claimed device in the same manner as intended by applicant. Said clauses are generally narrative and do not further structurally limit the apparatus.

7. The reagent in the container in claims 8 and 47 is not recited as part of the claimed apparatus.

8. Regarding claims 25, 26, 27, 29, 30, 31, 64, 65, 66, 68, 69 and 70, [claims 25 and 64] “for adapting the inflowing air with predetermined characteristics;” [claims 26 and 65] “ensuring high and uniform humidity in the chamber when...” (the phrase when implies the conditional usage of the device); [claims 27 and 66] “controls humidity by spraying water droplets or having a water surface;” [claims 29 and 68] “controls the humidity to never be below a predetermined level, to prevent drying out of the sample;” [claims 30 and 69] “for adding disinfectants, UV protectants or other compounds may be added to the inlet air to prevent microbial growth or discolouring;” and [claims 31 and 70] “addition of fluids from the group consisting of reagents, neutral gas, oxygen, carbon dioxide, nitrogen, water droplets, and formamide,” which are directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art.

9. It is noted that there are no specific structures disclosed for the ventilation, air manipulation, exhaustion and pressure control devices. The disclosure only discloses that the apparatus may be connected to devices that are capable of ventilating, controlling pressure, and manipulating air. It is also noted that the phrase “environment

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of interior space” in claims 1 and 40 is rather broad and is not only limited to the condition of the air inside of the apparatus.

Claim Objections

10. Regarding claims 17 and 56, it is unclear if the element "a fan" is same as or part of the exhaustion device in claims 16 and 55 or some other device (See specification; new figures; and applicant's remark filed 6/7/10). Thus the recitation should be more so "wherein the exhaustion device comprises a fan..." It also appears that the ducts are the air inlet/outlet. Appropriate correction is required.

Drawings

11. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the covers that are capable of defining multiple closed interior spaces (claims 7, 8, 46 and 47) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

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changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner cannot find any support for the limitations "wherein a first sample, in a first drawer, for which the processing is completed may be removed from the apparatus without interrupting the ongoing robotic processing of a second sample in a second drawer, and wherein a/the second sample, in a/the second drawer, may be inserted into the apparatus without interrupting the dispensing of reagents onto a/the

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first sample, in a/the first drawer, with the robotic reagent dispensing head”
(specification in the instant or provisional application).

The limitation "removed from the apparatus" in the amended claim implies that the drawers are removed from the housing of the apparatus (i.e., placed outside of the interior space defined by the cover and the housing containing a robotic processing device). It is not clear if applicant means that the drawers are removed from the processing (staining) station within the apparatus/housing; or the drawers are displaced to the outside of the housing (in which the condition of the enclosed interior space is being monitored) by opening the cover.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 40, the recitation "at least one slide" in line 6 renders said claims unclear, because it is not clear if it is the same "at least one slide" recited in line 4 of the of claims 1 and 40 or some other slides. It appears that "said /the" is missing before "at least one slide" in line 6.

Furthermore, regarding claim 1, it is unclear if "a second sample in a second drawer" recited in line 25 is same as "a second sample in a second drawer" recited in line 26 (The same applies to "a first sample in a first drawer" in lines 23 and 27: See claim 40).

Regarding claims 17 and 56, it is unclear whether the inlet opening is or part of the ducts recited in claims 16 and 55. The claims recite them as different structure. However according to the specification, they are more so directed toward the same elements or part of the same elements (i.e., part of the manifold that establishes communication between interior and exterior: 123, 123).

Regarding claim 40, the term “staining section” does not inherently impart any specific structural requirement. It is unclear how such a section can be referenced a “staining” portion of the apparatus. The element of said claim does not structurally limit the section to a particular processing or staining section. The phrase “staining” implies the intended use of said sections.

Furthermore, it is noted that the preamble of claim 40 recites an automatic staining device. However claim 40 includes no structures directed towards staining or automating staining structures.

Claim 7 (or claim 46) recites a plurality of sections. It is unclear if said sections is/are the at least one processing sections, subject to processing by the robotic processing device recited in claims 1 and 7 (claims 40 and 46), or some other sections.

Regarding claims 8-11 and 47-50, it is unclear what is meant by “a plurality of interior space” or “each interior space.” The new drawing (Fig. 1) and the disclosure depict that the cover is merely partitioned into multiple parts. The interior space under the partitioned cover is one interior space containing a robotic processing device, in which the space comprises multiple sections. It appears that if one of the cover is open, then the entire space is open to the outside environment. Claims 1 and 7 (or claims 40

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and 46) recite that the cover is a plurality of covers that cover the housing to define an interior space. There is no recited or claimed structural element(s) that requires the covered housing defining interior space to be partitioned into multiple closed interior spaces by the plurality of cover or the housing (which is implied by the phrase “each interior space”). The examiner cannot find such a structure depicted in the drawings.

Regarding claims 22, 23, 61 and 62, it is noted that claims 19 and 58 recites that the exhaustion device removes/withdraws fumes from the interior space (housing). Thus it is somewhat unclear to recite that the exhaustion device draws air from outlet.

Regarding claims 32 and 71, it is not clear if “a carrier rack” is the same carrier rack recited in claims 1 and 40 or some other carrier.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-25, 27, 29-32, 40-64, 66 and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungmann (US 6017495) in view of Fish (US 5946221); and in further view of Tseung (US 20030099573).

Regarding claims 1-25, 27, 29-32, 40-64, 66 and 68-71, Ljungmann discloses (abstract; and Figs. 1-5) a staining apparatus for staining of tissue specimens placed on microscope slides comprising a number of staining stations (4) comprising drawers (21) with carriers (5, 9); and other working stations (1, 2, 3). The device includes a program-controlled staining process (abstract; and disclosure). The multiple cover (Fig. 2: 33 and 35) defines an interior space(s) over the number of processing stations and the housing (The examiner also asserts that dividing the cover into multiple sections to hover over each processing station is obvious. Separating a device into multiple parts that were integral involves only routine skill in the art. As to the seal on the cover, Ljungmann teaches the environmentally and operator friendliness of the invention (C4/L18-35).

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Providing a seal for the cover to prevent the leak of toxic reagent is obvious). The stations are heated by means of hot air supplied from a fan 15 in combination with a heating element (C2/L47-49; and Fig. 2). The apparatus is also provided with an exhaustion/ventilation (32) comprising a ventilating fan which is combined with a filter system for absorption of gases from solvents (C4/L36-45: The 32 with inlet/outlet both below and above the slide accommodation). The cover (33+35) is hinged at the upper rear edge of the apparatus and in addition is coupled to a pair of gas damping cylinders 34 (C4/L36-45). Water is supplied to the vessels (9) via water filling pipes (10) communicating with a water intake (11). Further, in connection with the vessels 9, there is arranged a drain hose 11 for drainage of sprinkling water from the rinsing baths (C2/L38-45). This hose is connected to a water outlet (13).

Ljungmann does not explicitly disclose an interior air/environment condition detecting sensors with a controller for controlling the disclosed ventilation system or heated air supply fan. (However, the controller for controlling the Ljungmann's ventilation or water additive system is obvious, and it will have to part of the staining procedure controller [36+37].)

Fish discloses a climate control device controlled by the computer/processor receiving data from the sensors detecting the climatic parameter for controlling environment under fume hood(s). The system comprises a device for controlling air flow through the fume hood based on air flow face velocity (abstract). The controlling device has a device for measuring pressure at the face of the fume hood which produces a signal corresponding to the pressure (id.).

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For example, Fish discloses an apparatus (abstract; and C3-C17) comprising:

- a housing frame (Fig. 1: 12 the lab; or the fume hood 14 in the lab with sliding cover in Fig. 18);
- at least one sample processing section, said at least one sample processing section is provided within said housing (The interior of the lab, 12, where technicians perform bio/chemical processing);
- at least one climate control device for controlling the environment within said interior space (controlled fume hoods);
- internal sensor devices for providing feedback signals to the climate control device (C3/L21-32);
- a data processing device for controlling the at least one climate control device and storing a processing protocol (e.g., C3/L32-45);
- wherein the sensor device is a temperature, a pressure, an airspeed, or a fume sensor (C3/L21-32);
- wherein the sensor device comprises internal sensors located inside the interior space (C3/L21-32);
- wherein the sensor device comprises external sensors located at an air inlet/outlet (C3/L21-32; and Fig. 2; 28);
- wherein the at least one climate control device includes a pressure control device for controlling at least the pressure (e.g., C3/L32-45);
- wherein the at least one climate control device includes humidity control within the interior space (e.g., C6/L4-19);

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- wherein the at least one climate control device includes a temperature control device for controlling the ambient temperature of the air within the interior space (e.g., C6/L4-19);
- wherein the climate control device comprises a ventilation system (fan) with an exhaustion device having a plurality of ducts (the controlled fume hoods communicating with exterior: See Fig. 2; A fume hood will have to have a fan);
- wherein the ventilation system comprise a fan in an opening (The fume hood or the air supply will have be provided with fans);
- further comprising at least one air manipulation device (See entire disclosure);
- wherein the climate control device comprises an exhaustion device capable of removing fumes from the interior space (the fume hood: also the fume hood exhaustion duct is placed above the hood and leaves the lab in ceiling);
- wherein the climate control device comprises a device fore toxic control (the fume hood), temperature, humidity control (e.g., C6/L4-19);
- wherein the device configured to recycle air comprises a filter capable of cleaning the air (All air supply (left portion of Fig 2) includes filters.);
- wherein an inlet comprising at least one air inlet opening in the housing frame (Fig. 2: the inlet shown in the left portion), and wherein an air manipulation device are provided in said inlet (C6-C17: See heated air supplied from supply duct.);
- wherein the air manipulation device comprises an air recycling device (See entire disclosure);

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- wherein the air manipulation device comprises an air additive supply (water droplets) device (All labs are equipped with fire extinguishing devices and sprinklers.); and
- wherein the apparatus comprises at least one sensor device, said sensors being arranged in the vicinity of the cover means and/or in the vicinity of the sample carriers on a carrier rack assembly (The sensors are relatively all in the vicinity of the cover/door and the processing section.).

The general climate control (ventilation) is taught by Ljungmann. Ljungmann also teaches that operator should not be exposed to harmful fumes from the bath solutions in the vessels (C1/L45-48).

It would have been obvious to one having ordinary skill in the art at the time of the invention to monitor the interior temperature or air condition (not visible to human eyes) using sensors and couple the sensor to a controller to automate the environmental control.

Modified Ljungmann teaches a robotic processing mechanism (Ljungmann: transport mechanism C3/L3-C4/L17). In device of Ljungmann, the chemicals are provided in the dying bath and drained. However modified Ljungmann does not disclose that the reagents may be supplied by a robotic dispensing head.

However, dispensing of staining reagents using a robotic pipetting head in an automated tissue staining system for staining tissue specimens carried by slides is well known in the art (Tseung: [0027]; [0031]; and [0032]. Also see US 6495106; and US 5439649).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of modified Ljungmann to incorporate a robotic reagent dispensing assembly.

20. Claims 26, 28, 65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungmann (US 6017495) in view of Fish (US 5946221); in further view of Tseung (US 20030099573); and in further view of Denison (US 1829341).

Regarding claims 26, 28, 65 and 67, modified Ljungmann discloses all of the limitations as set forth above.

Modified Ljungmann teaches the humidity control. However modified Ljungmann does not teach the use of humid filter to maintain the high interior humidity.

Denison discloses an air conditioning (heating) device comprising a humid/moist filter (e.g., page 1, lines 21-25 and 65-75) for ensuring the proper interior humidity.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the humidity control device taught by Denison to the device of modified Ljungmann, for the purpose of preventing low interior/ambient air humidity.

Response to Arguments

21. Applicant's arguments filed 2/15/2011 have been fully considered.

22. The objections to the claims 11, 25, 50 and 64 are withdrawn. The objections to claims 17 and 56 are maintained. The exhaustion device in view of the specification appears to be or appears to include the fan, i.e., the device capable of drawing air from

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the interior or exchanging air (If air is drawn, air must enter from some place.). It also appears that the ducts are the air inlet/outlet, which is part of the manifold.

Otherwise, the claimed limitation "fan" lacks antecedent basis in the specification.

23. The 112 rejections from the previous rejections are withdrawn.

24. Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

25. The references cited by applicants in the IDS and listed on the numerous 1449's have been made of record. While the statements filed clearly do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material, rather they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references, however, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure, see *Penn Yan Boats, inc. V. Sea Lark boats Inc.*, 359 F. Supp. 948, aff'd 479 F. 2d. 1338.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

4/20/11

/Brian R Gordon/

Primary Examiner, Art Unit 1773